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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/756,925	01/09/2001	Christian Quellet	12846/121488	6779

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EXAMINER	
YU, GINA C	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 05/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/756,925	QUELLET ET AL.	
	Examiner	Art Unit	
	Gina C. Yu	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-27 and 29-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-27 and 29-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 27, 2004 has been entered.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 2-27 and 29-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsuei et al. (US 5589194) ("Tsuei") in view of Lee (US 5508041) and Carlsson (US 6838089).

Tsuei teaches microcapsules having water-soluble or insoluble active components dissolved or dispersed, respectively, in solid thermoplastic matrix. See abstract; col. 3, line 21 – col. 4, line 67. See also Example 7, which teaches microcapsules containing beta-carotene in vegetable oil. The reference also teaches the method of making microcapsules via extrusion process. See col. 3, line 64- col. 4, line 7. See instant claims 11-13. The reference also teaches that the amount of the active components and size of the microcapsule can be controlled by the prior art process. See col. 3, lines 27 – 39. The reference teaches that the amount of active

component to be incorporated in microcapsules may be readily and closely controlled by adjustment to the concentration in the encapsulation composition before injection of the stream. See col. 3, lines 31 – 35. The active components to be encapsulated are taught in col. 4, lines 21-37. See instant claim 26, 27, 36. The reference teaches that the microencapsules provide good controlled-release because these are uniform and small in size, and further teaches that a small core is particularly preferred when immediate release by enzymes such as those contained in the stomach is desired. See col. 9, lines 43 – 47.

Tsuei fails to teach the size of the inclusion of the microcapsules.

Lee teaches method of making microencapsulated emulsion of drug-dispersed oil core surrounded by a water-soluble polysaccharide (thermoplastic) capsule material. See abstract. The reference teaches that drugs is mixed with liquid oil by sonication; and the oil-in-water emulsion containing the drug dispersed oil droplets are produced by sonication of oil/aqueous solution mixture. The oil droplets are said to be 1-5 microns. The reference teaches using Tween 20, Tween 40, and Tween 80 (sorbitol ester of a fatty acid) to make stable oil-in-water emulsion. See col. 3, line 63 – col. 4, line 7. The amount of the emulsifiers to be used is also disclosed therein. See instant claims 38-31-33. The reference teaches using active ingredients in an amount of 1-40 % of the liquid oil. See col. 3, lines 54 – 62. See instant claims 31-33.

When the prior art discloses a range which touches, overlaps or is within the claimed range, but no specific examples falling within the claimed range are disclosed,

a case by case determination must be made as to anticipation. See MPEP 2131.03. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. See In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). "[A] prior art reference that discloses a range encompassing a somewhat narrower claimed range is sufficient to establish a prima facie case of obviousness." See In re Peterson, 315 F.3d 1325, 1330, 65 USPQ2d 1379, 1382-83 (Fed. Cir. 2003). In Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. In this case, since the claimed size of inclusions partly overlaps with the size of the oil droplets of Lee, making microencapsulants of the claimed invention is viewed obvious over the prior art.

Lee fails to teach extrusion method.

Carlsson teaches that it is well known in pharmaceutical art that sonication and extrusion are interchangeably used to make emulsions. See col. 6, lines 8 – 22.

Given the teaching in Tsuei that small core is preferred for immediate release, it would have been obvious to one of ordinary skill in the art at the time the present invention was made to have modified the prior art invention to produce microcapsules with small core size. The skilled artisan would have been motivated to produce the

microcapsules with the recited inclusion size and use emulsifiers as motivated by Lee because the reference teaches producing microcapsules with the inclusion size of 1-5 microns. It would have been obvious to one of ordinary skill in the art that the Tsuei extrusion method would produce the small inclusion size because Carlsson teaches that extrusion and sonication are exchangeably used in making emulsion particles.

Examiner notes that claims 2, 3, 29, 30 are product by process claims. It is well known in patent law that "even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." See In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In this case, claims 29 and 30 are rejected here because the recited method is not give patentable weight, and the powdery microencapsulated composition meets the limitation of the recited composite material.

For claim 10, it is generally considered prima facie obvious to combine two compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. See In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980). As shown by the recited teaching, the instant claims define nothing more than the concomitant use of

two biological actives for controlled-release. It would follow that the recited claims define prima facie obvious subject matter.

2. Claims 40 and 41are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsuei, Lee, and Carlsson as applied to claims 2-27 and 29-39 above, and further in view of Bilbrey (US 5290547).

Tsuei, Lee, and Carlsson fail to teach using co-surfactants as recited in the instant claims.

Bilbrey teaches odor-masking products comprising coated oil-in-water emulsion droplets of fragrance oil for the use odor masking products. See abstract; col. 1, line 61 – col. 2, line 55. The reference teaches that the size of the droplets is in the range of 2-300 μm. See col. 3, lines 11 – 26. Adding emulsifiers such as sodium lauryl sulphate, sorbitan tristearate, sorbitan trioleate or sorbitan monooleate for surfactants is disclosed in col. 4, lines 54 – 65. The amount of actives, water, surfactant, and additives in microemulsion is disclosed in col. 5, lines 29-41.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composite materials of the combined references by adding the surfactants as suggested by Bilbrey, because of the expectation of successfully producing a uniform dispersion of active ingredients in the composite materials.

Response to Arguments

Applicant's arguments with respect to claims 2-27, 29-41 have been considered but are moot in view of the new ground(s) of rejection in part and unpersuasive in part.

Applicants assert that the Tsuei method produces encapsulants having sizes 400-1500 microns at best. Examiner respectfully notes that no such disclosure is found in the record. As indicated in the above rejection, the reference teaches that the shape and size can be closely controlled, and microencapsules having the size in the obvious range as the claimed invention are already known in the art. The process and the product as claimed are not patentably distinct from the collective teachings of the prior arts.

Applicants assert that Bilbrey fails to teach the claimed invention "as a whole". The present rejection is made in view of the collective teachings of four references, and Bilbrey is simply cited to show that applicants' co-surfactants are well known in microcapsule art.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-0635.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gina Yu
Patent Examiner

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER